



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 21, 2020

Rebekah Baska
Registration Specialist
S.C. Johnson & Son, Inc.
1525 Howe St.
Racine, WI 53403-2236

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Nightline 2.0
EPA Registration Number: 4822-614
Application Date: 03/19/2020
Decision Number: 560896

Dear Ms. Baska:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

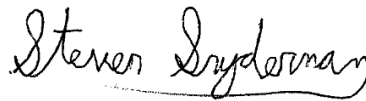
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rotavirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive, flowing style.

Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

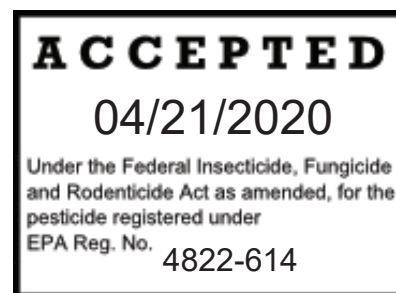
Enclosure: stamped label

EPA MASTER LABEL

Nightline 2.0

Alternate Brand Names:

- Power Stain Destroyer Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Tough Stain Remover Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Advanced Stain Fighter Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Pro Stain Fighter Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Stain Destroyer Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Stain Eliminator Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Total Stain Remover Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Heavy Duty Non-Bleach Toilet Bowl Disinfectant (Cleaner)
- Power Stain Destroyer Toilet Bowl Disinfectant (Cleaner)



ACTIVE INGREDIENTS

Hydrochloric Acid.....6 %

OTHER INGREDIENTS94 %

TOTAL.....100%

KEEP OUT OF REACH OF CHILDREN

DANGER: See (back) (inside) (panel for) additional precautionary statements (including first aid) (and complete use instructions) on back

Net Wt. (XX mL) (X OZ)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

1. Lift the toilet seat
2. To remove the cap, squeeze the two side surfaces and unscrew completely
3. (Add) (Direct) 10 ounces of liquid gel (product) under the rim and squeeze evenly around the bowl.
4. TO DISINFECT: Allow to sit for at least 10 minutes.
5. TO CLEAN TOUGH STAINS: Allow to sit for at least 15 minutes. (In case of very tough stains, reapply and leave overnight.)
6. Brush the entire bowl, then flush.
7. To close cap, turn to secure tightly.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place that is inaccessible to children and pets.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available. If partially filled: Call your local solid waste agency or 1-800-529-3394 for disposal instructions.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

S.C. Johnson & Son, Inc.

File Name: Nightline 2.0

EPA Reg. No. 4822-614

REB 3.19.20

Page 1 of 9

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear protective clothing and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before use.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not store near heat or open flame. Do not use with or store near any oxidizing or reducing agents. Never use or mix with other household cleaners as hazardous fumes may result.

Questions? Comments? Call 800-558-5252 or Write Helen Johnson

Made in Mexico. Sold by: ©[year] S.C. Johnson & Son, Inc., Racine, WI 53403-2236

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EPA Reg. No. 4822-614

EPA Est. No.

[website may be listed]

[Optional Marketing Claims]

[Note to Reviewer: "And" or "&" can be used interchangeably in the marketing sentences. Sentences may be joined using the word "and" or "or" or comma's. Exclamation marks may be used for emphasis. All claims containing the word "new" or "improved" will only be used for 6 months after the first retail production.]

[Note to reviewer: **Type** claims may be qualified by using the **Name** from the following list:]

Type	Name	ATCC
Bacteria	<i>Staphylococcus aureus</i> (Staph)	ATCC 6538
	<i>Salmonella enterica</i> (Salmonella)	ATCC 10708
	<i>Pseudomonas aeruginosa</i> (Pseudomonas)	ATCC 15442
	<i>Enterobacter aerogenes</i>	ATCC 13048
	<i>Escherichia coli</i> (O157:H7) (E. coli)	ATCC 35150
	<i>Enterococcus faecalis</i>	ATCC 29212
	<i>Proteus mirabilis</i>	ATCC 9240
	<i>Shigella dysenteriae</i>	ATCC 11835
	<i>Shigella flexneri</i>	ATCC 9380
	<i>Serratia marcescens</i>	ATCC 14756
Viruses	Herpes Simplex Virus Type 1	ATCC VR-733
	Herpes Simplex Virus Type 2	ATCC VR-734
	Influenza A (H1N1) Virus (Influenza) (Flu)	ATCC VR-1469
	Rotavirus (Strain WA)	ATCC VR-2018

*(Bacteria)(:) (*Staphylococcus aureus*) (Staph) (ATCC 6538), (*Salmonella enterica*) (Salmonella) (ATCC 10708), (*Pseudomonas aeruginosa*) (Pseudomonas) (ATCC 15442), (*Enterobacter aerogenes*) (ATCC 15442), (*Escherichia coli*) (O157:H7) (E. coli) (ATCC 35150), (*Enterococcus faecalis*) (ATCC 29212), (*Proteus mirabilis*) (ATCC 9240), (*Shigella dysenteriae*) (ATCC 11835), (*Shigella flexneri*) (ATCC 9380), (*Serratia marcescens*) (ATCC 14756)

†(Germs)(:) (*Staphylococcus aureus*) (Staph) (ATCC 6538), (*Salmonella enterica*) (Salmonella) (ATCC 10708), (*Pseudomonas aeruginosa*) (Pseudomonas) (ATCC 15442), (Herpes Simplex Virus Type 1) (VR-733), (Herpes Simplex Virus Type 2) (VR-734), (Influenza A) (H1N1) (Virus) (Influenza) (Flu) (VR-1469), (Rotavirus) (Strain WA) (VR-2018)

[Information in brackets is notes to Reviewer]

(Information in parenthesis is optional language)

^(Viruses)(:) Herpes Simplex Virus Type 1 (VR-733), Herpes Simplex Virus Type 2 (VR-734), Influenza A (H1N1) Virus
(Influenza) (Flu) (VR-1469), Rotavirus (Strain WA) (VR-2018)

{Note to Reviewer: These statements for claims against large, non-enveloped viruses, shall not appear on marketed (final print) labels.}

EMERGING VIRAL PATHOGENS

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped viruses

For an emerging viral pathogen that is a/an...	...follow the direction for use for the following organism on the label
Enveloped virus	Rotavirus

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard non-porous surfaces. Therefore, **[Product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against Rotavirus on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

OR

[Name of illness/outbreak] is caused by **[name of emerging virus]**. **[Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the direction for use against Rotavirus on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

Disinfecting claims:

- Antibacterial (Disinfecting) formula
- Bacteria*-fighting (germ-fighting[‡]) (Virus-fighting[^]) Formula
- Toilet Bowl Cleaner (Disinfectant)
- 100% Limescale Destroyer Toilet Disinfectant
- Antibacterial (Antimicrobial) (Bactericidal) (Bactericide) (Disinfectant) (Disinfects) (Germicidal[‡]) (Virucidal[^]) Action
- Cleans (disinfects) above and below the waterline
- Cleans as it disinfects
- Controls toilet odors (at their source) caused by bacteria*
- Deodorizes by killing bacteria* that cause odors
- Disinfects and breaks down stains
- Disinfects (your toilet) (your toilet bowl)
- Disinfects and deodorizes by killing bathroom germs[‡]
- Disinfects in hard to reach areas (like) (under the rim) (and) (into the 'S' bend)
- Disinfects toilets (bidets) (and) (urinals)
- Easily and effectively disinfects toilet bowls (and urinals)
- Great for everyday cleaning (deodorizing) (disinfecting)
- (Home) disinfectant toilet bowl cleaner
- Kills (99.9% of) viruses[^] and bacteria*
- Kills (the) most common germs[‡]
- Kills 99.9% of bacteria* (and Viruses[^])
- Kills 99.9% of bacteria* (and) (viruses[^])
- Kills 99.9% of germs[‡]
- Kills bacteria*
- Kills odor-causing bacteria*
- Kills the bacteria* that cause bad odors
- Leaves toilet bowl clean and disinfected
- Reaches hidden germs[‡] (and) (stains) (grime) under the rim

Cleaning claims:

- Completely (Effectively) (Thoroughly) Cleans (and Deodorizes)
- Deep cleaning (Easy to use) (Rust destroying) (Thick) (Tough stain) Formula
- Deep cleaning (Easy to use) (Rust destroying) (Thick) (Tough stain) Formula Breaks down (Cleans) (Cleans away) (Destroys) (Dissolves) (Easily) (Penetrates) (Removes) (Stubborn) (Tough) Hard Water (Lime Scale) (Mineral) (Rust) (Stains) (Deposits) (Toilet Rings)
- Destroys (Dissolves) toilet bowl rings
- Destroys (Dissolves) tough rust (stains) and mineral deposits

S.C. Johnson & Son, Inc.

File Name: Nightline 2.0

EPA Reg. No. 4822-614

REB 3.19.20

Page 6 of 9

- Destroys (Eliminates) (Powers Through) hard water (Tough) (the Toughest) stains
- Get (Make) it clean, keep it fresh (clean)
- Get (Make) your toilet clean with [Insert Product Name], and keep it fresh (Clean) with Scrubbing Bubbles® Toilet (Cleaning) (Fresh) Gel (stamp)
- (Helps) Remove(s) Toilet Rings
- (It's) (It is) Cleaning Reinvented Lime (Rust) (Scale) Remover
- (New) [Insert Product Name], all the tough cleaning power you need for impeccable results even against the toughest stains.
- Powerful Clean (Cleaning action)
- Changes Colors while it works (cleans)
- Cleans away everyday dirt and grime
- Cleans without Bleach(ing)
- Deodorizes with a fresh, clean scent
- Designed to clean under the rim
- For a clean toilet bowl
- For a super (thoroughly) clean toilet (bowl) (surface)
- Formulated especially for hard water mineral deposits, lime scale and rust
- For hard water stains (areas)
- Heavy-duty (cleaner) (cleaning) (formula)
- Leaves a sanitary (clean) (and fresh) toilet
- Powerful cleaner for the toilet bowl
- Powerful cleaning formula (dissolves) (destroys) (removes) (tough stains) (rust stains) (mineral stains)
- Powers through Limescale, Rust and Tough Stains for impeccable results
- Quick and easy cleaning
- Removes the toughest stains
- Removes (Destroys) 100% (of) Limescale
- Removes (Destroys) 100% (of) Rust
- Removes (Destroys) the Toughest Stains
- Specially designed for hard water (problems) (stains) (areas)
- Specially designed for the removal of rust (stains) (limescale stains) (mineral deposits)
- Specially designed neck makes it easy to clean under the rim
- Specially designed to breakdown (stains) (rust) (limescale stains) (mineral desposits)
- Specially designed to clean the toilet
- Tough Cleaning Power

Miscellaneous Marketing claims:

- Triple (3) Pack
- Twin (2) Pack
- Value (bonus) Pack
- Changes color before your eyes (as it works)!
- Coats the entire bowl
- Easy Reach Neck under the rim
- Easy to reach under the rim
- Evenly coats the toilet for 360° coverage, even under the rim
- Extended Reach Neck (under the rim)
- No unwanted toilet cleaner smell
- We work hard so you don't have to (TM or ®)
- With refreshing Scrubbing Bubbles® fragrance
- X Uses (per) (pack) (bottle)
- S.C. Johnson (& Son) (A Family Company) (Wax)(since 1886) (Fisk Johnson [signature])
- Peel (remove) (tear) label (sticker) (coupon) (here) for complete use directions
- Peel (remove) (tear) label (sticker) (coupon) (here) for complete use directions and precautionary statements
- Peel (remove) (tear) label (sticker) (coupon) (here) before use
- Citrus [fragrance descriptor]
- Rainshower [fragrance descriptor]

Graphics:

